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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

ROCHESTER DRUG COOPERATIVE, INC.,

Defendant.

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15 Civ. 5219

COMPLAINT

Plaintiff, the United States of America, by its attorney, Preet Bharara, United States Attorney for the Southern District of New York, alleges upon information and belief as follows:

INTRODUCTION

1. The United States of America brings this civil enforcement action seeking penalties and injunctive relief against defendant for violating the Controlled Substances Act, as amended, 21 U.S.C. §§ 801 *et seq.* (the "Act" or "CSA"), and its implementing regulations, 21 C.F.R. §§ 1301 *et seq.* (the "Regulations"). As set forth more fully below, the United States alleges in this action that defendant Rochester Drug Cooperative, Inc. ("RDC"), a controlled

substances distributor headquartered in Rochester, New York, engaged in repeated violations of the Act and Regulations with regard to the filing of required Schedule II (and certain Schedule III) controlled substances reports and related records.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 21 U.S.C. §§ 842(c)(1) and 843(f)(2), and 28 U.S.C. §§ 1345 and 1355.

3. Venue is proper in the Southern District of New York pursuant to 21 U.S.C. § 843(f)(2) and 28 U.S.C. §§ 1391(b) and 1395(a).

THE PARTIES

4. Plaintiff is the United States of America.

5. Defendant RDC is a pharmaceutical distributor located in Rochester, New York. RDC engages in interstate distribution of, among other things, controlled substances as defined under the Act, pursuant to Drug Enforcement Administration ("DEA") registration number PR0003032. *See* 21 U.S.C. § 802(6); 21 C.F.R. § 1308.12. RDC regularly distributes scheduled controlled substances to pharmacies that conduct business in the Southern District of New York.

REGULATORY BACKGROUND

6. Drugs and other substances that are considered controlled substances under the CSA are divided into five "schedules," generally designated by Roman numerals I through V. Schedule II controlled substances, as defined under the Act, are drugs that have a currently accepted medical use in the United States, but also a high potential for abuse, which may lead to severe psychological or physical dependence. *See* 21 U.S.C. § 812(b)(2).

7. To combat the high potential for abuse of Schedule II controlled substances, the Act creates a distribution monitoring system for those authorized to handle controlled substances, at the heart of which are registration and tracking requirements. The Act mandates strict adherence to a number of these requirements by any person or entity that distributes controlled substances.

8. A distributor is a person or an entity that delivers (other than by administering or dispensing) a controlled substance. Delivery is the actual, constructive, or attempted transfer of a controlled substance. *See* 21 U.S.C. §§ 802(8), (11).

9. Among the requirements for a person or entity that distributes controlled substances is mandatory registration. Specifically, distributors of controlled substances must register with the DEA, which is thereafter authorized to inspect the registrant's establishment to ensure compliance with the applicable Regulations and other rules and requirements. *See* 21 U.S.C. §§ 822(a)(1), (f).

10. DEA's Automation of Reports and Consolidated Orders System ("ARCOS") is an automated, comprehensive drug reporting system which monitors the flow of Schedule II (and certain Schedule III) controlled substances (together, the "ARCOS Reportable" controlled substances) from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level. ARCOS accumulates data on distributors' controlled substances acquisition/distribution transactions which are then summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution. *See* 21 C.F.R. §§ 1304.33(a), (c) & (e).

11. Each person or entity that is registered to distribute ARCOS Reportable controlled substances must report acquisition and distribution transactions using DEA Form 333 every

quarter. ARCOS is an automated, electronic equivalent of DEA Form 333 that allows distributors to file their acquisition and distribution transaction reports with the DEA electronically. *See* 21 U.S.C. § 827(d)(1); 21 C.F.R. §§ 1304.33(a), (b).

12. Acquisition and distribution transaction reports must provide data on each acquisition to inventory (identifying whether it is, *e.g.*, by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, *e.g.*, by sale or transfer, theft, destruction or seizure by Government agencies) for each ARCOS Reportable controlled substance. *See* 21 U.S.C. § 827(d)(1); 21 C.F.R. §§ 1304.33(e), (d).

13. A facility's "inventory" consists of all factory and branch stocks in finished form of a basic class of controlled substance acquired by a registrant, whether contained in bulk, in commercial containers, or in pharmaceutical preparations in the possession of the registrant (including stock held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor). *See* 21 C.F.R. § 1300.01(b).

14. Inventory that has been lost or stolen must also be reported separately to DEA within one business day of discovery of such loss or theft. *See* 21 C.F.R. § 1301.76(b). Registrants are required to report such losses through DEA Form 106, which DEA encourages registrants to file online, to reduce the possibility of error. *See e.g.*, http://www.deadiversion.usdoj.gov/21cfr_reports/theft/.

15. Schedule II controlled substances are distributed or ordered one of two ways – either by dispensing entities using a paper order form issued by DEA, known as "Form 222," or using the electronic equivalent, the DEA Controlled Substance Ordering System ("CSOS"). *See* 21 U.S.C. § 828(c)(1)-(2); 21 C.F.R. § 1305.03.

16. Registrants who wish to order or distribute Schedule II controlled substances electronically must separately register for the CSOS maintained by DEA. *See* 21 C.F.R. § 1311.25. Registration for CSOS includes an agreement by the registrant to abide by all DEA rules and regulations specific to CSOS.

17. DEA issues eligible individuals and entities who register for CSOS a digital certificate and private key, allowing that person or entity to "sign" orders for controlled substances. *See* 21 C.F.R. §§ 1300.03 and 1311.05.

18. Entities dispensing Schedule II controlled substances that utilize electronic order forms through CSOS must, upon receipt of a shipment, reconcile the shipment with existing inventory by creating a record of the quantity of item received and the date received. This record must be electronically linked to the original order and archived. *See* 21 C.F.R. §§ 1305.22(g), 1311.60(a).

19. In addition to filing acquisition/distribution transaction reports, each person or entity that is registered to distribute Schedule II controlled substances must maintain "on a current basis a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of." *See* 21 U.S.C § 827(a)(3); 21 C.F.R. §§ 1304.21(a), 1304.22(b), (a)(2).

20. Each record must be available and kept at least two years for inspection by the DEA. *See* 21 U.S.C. §§ 827(b) and 828(c); 21 C.F.R. §§ 1304.04 and 1305.17.

21. It is unlawful for any person "to refuse or negligently fail to make, keep or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information" required by the Act. *See* 21 U.S.C. § 842(a)(5).

22. Violations of requirements under the Act carry a per-violation penalty of up to $10,000, as well as injunctive relief. *See* 21 U.S.C. §§ 842(c)(1)(B) and 843(f).

FACTS

23. DEA's New York Field Division conducts audits and inspections of registered facilities, including pharmacies, pursuant to the Act. During the relevant time period, DEA visited several pharmacies in New York City that reported the routine electronic purchase of ARCOS Reportable controlled substances from distributor RDC.

24. DEA's pharmacy audits discovered that these pharmacies had purchased ARCOS Reportable controlled substances from RDC on many thousands of occasions, but RDC had failed to electronically report to DEA their corresponding distribution of the same ARCOS Reportable substances to the pharmacies DEA had audited.

25. DEA's New York Field Division went on-site at RDC to investigate. On or about July 31, 2013, DEA agents and investigators conducted a two-day administrative inspection of RDC's facility in accordance with 21 U.S.C. §§ 822(f) and 880.

26. During the inspection, DEA found that defendant RDC had violated the Act and the Regulations by not providing acquisition/distribution transaction reports in ARCOS or on DEA Form 333 in accordance with 21 U.S.C. § 827(d)(1) and 21 C.F.R. § 1304.33.

27. During the inspection, RDC was also unable to provide complete ARCOS records to DEA investigators in accordance with 21 U.S.C. § 827(b) and 21 C.F.R.§ 1304.04.

28. RDC responded that its failure to electronically report certain ARCOS data was likely due to a computer software problem. RDC also responded that it expected to be able to resolve this problem through the pending acquisition of a new order system. DEA therefore

deferred administrative and/or civil action at that time, to ascertain whether RDC's new system would potentially resolve the issue.

29. DEA reassessed RDC's compliance in 2014. DEA discovered that RDC had not implemented its new order system. As a consequence, RDC's failure to report the distribution of thousands of electronic Schedule II and certain Schedule III orders in ARCOS remained on-going. During this time, DEA also determined that RDC had for years failed to report the theft or significant loss of controlled substances in its ARCOS reporting.

30. In June 2014, DEA audited RDC's reporting compliance by matching reportable orders of Schedule II controlled substances in CSOS with the ARCOS reports that were filed by RDC. Each reportable order of a Schedule II controlled substance by a pharmacy or pharmacist in CSOS should match to a single acquisition/distribution transaction report filed by the distributor in ARCOS.

31. When DEA compared RDC's reportable orders in CSOS with RDC's filed acquisition/distribution transaction reports in ARCOS, DEA's audit found that RDC had failed to report in ARCOS thousands of transactions that were reported in CSOS.

32. In sum, DEA discovered that RDC's ARCOS reports had failed to report any electronic orders that had been placed through CSOS. Moreover, for several years, RDC failed to include any theft and loss information in its ARCOS reporting.

FIRST CAUSE OF ACTION

(Failure to Report Acquisition/Distribution Transactions – Multiple Violations)

33. For the five years ending on June 30, 2014, RDC failed to report acquisition/distribution transactions of controlled substances in ARCOS or failed to file DEA Form 333 with respect to many thousands of orders of ARCOS Reportable controlled substances.

34. RDC thus failed to provide data on each acquisition to inventory, each reduction from inventory, and the registration number assigned to the person or establishment to whom such sale, delivery, or other disposal was made on a quarterly basis, in violation of the periodic reports requirement codified at 21 U.S.C. §§ 827(d) & 842(a)(5) and 21 C.F.R. § 1304.33.

35. Each violation set forth above is subject to a penalty of up to $10,000.

SECOND CAUSE OF ACTION

(Failure to Report Theft or Significant Loss of Controlled Substances – Multiple Violations)

36. For five years ending on June 30, 2014, RDC failed to report controlled substances theft and loss data in its periodic ARCOS reporting to DEA. *See* 21 C.F.R. § 1301.76(b).

37. This violation occurred on multiple occasions, with the precise number of violations to be established at trial.

38. Each violation set forth above is subject to a penalty of up to $10,000.

WHEREFORE, the United States demands judgment in its favor and against RDC as follows:

(a) for a maximum statutory penalty in the amount of $10,000 for each of the violations set forth herein pursuant to 21 U.S.C. § 842(c)(1)(B);

(b) for appropriate injunctive relief pursuant to 21 U.S.C. § 843(f);

(c) for the costs of this action; and

(d) for such further relief as the Court may deem proper.

Dated: New York, New York
July 6, 2015

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